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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,398	08/03/2000	ABDESSATAR CHTOUROU	065691/0193	9759

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EXAMINER

MOHAMED, ABDEL A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/581,398

Applicant(s)

CHTOUROU ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 November 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 24-49 and 51.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13.

10. ☐ Other: _____


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Continuation of 3. Applicant's reply has overcome the following rejection(s): The objection to the specification and the rejection under 35 U.S.C. 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection under 35 U.S.C. 103(a) over the prior art of record is maintained. Applicant's arguments that the combined teachings of the prior art, particularly the primary reference of WO 96/00237 does not teach all the elements of claim 24, does not provide reasonable expectation of success in arriving at the present invention, or suggest the present invention of claim 24, and there is no nexus between factor VIII (FVIII) and a 15 nm. filter, nor any explicit or implicit suggestion that these two features are combinable into a single process, and as such, the prior art of record cannot support a prima facie establishment of obviousness is unpersuasive. Although, Applicant has limited independent claim 24 to filtering FVIII solution with virus filter having a mean pore size of 15 nm., however, contrary to Applicant's arguments, the primary reference of WO 96/00237 on page 8, lines 11-12 states that Planova 15 is used to remove small viruses, such as polio viruses. Further, on page 8, lines 14-20, the reference states that the choice of filter depends on the size of the protein concerned and recites various proteins having different molecular weights and among them FVIII. Hence, based on the molecular weights and the intended purpose of filtration (i.e., in the instant case, virus filtration and/or removal of viruses to make FVIII free of virus), one of ordinary skill in the art would be able to determine the appropriate filter size. Thus, the primary reference clearly teaches or suggests the use of various filters which are readily available commercially such as Planova 15 filter for virus filtration having a porosity as low as 15 nm. for the intended purpose of reducing and/or removing the content of very small non-enveloped viruses, such as parvovirus, polio virus, hepatitis virus, ect. in protein solution of interest which may include FVIII. Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to employ a method of obtaining a virus free solution of plasma protein complex of FVIII by combining a dissociation step and a filtration step using a filter with a porosity of 15 nm. in the manner claimed in the instant invention. Thus, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Haris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them". Thus, the rejection of claims 24-49 and 51 under 35 U.S.C. 103(a) over the prior art of record is maintained for the same reasons discussed in the previous Office action.